Remarks

Applicant has carefully considered this Application in connection with the Examiner's Action, and respectfully requests reconsideration of this Application in view of the foregoing amendment, and the following remarks.

Applicant has amended Claims 5 and 8. Claim 5 has been amended to recite a method of treating a condition characterized by substance-P induction. Claim 8 has been amended to properly present what compound is being made by the claimed process. Support for the amendments can be found in the specification as filed. Specifically, support for the amendment to Claim 5 can be found, for example, at paragraphs 0009 – 0017 of the Published Application (US 2006/0135558). Support for the amendment to Claim 8 can be found, for example, at paragraph 0024 of the Published Application (US 2006/0135558). No new matter has been added.

Accordingly, Claims 1-6, and 8 are presently pending in the Application.

I. Allowable Subject Matter

The Examiner has determined that Claims 1-4 and 6 are free of art, and hence are in condition for allowance.

II. Rejection of Claim 5 under 35 U.S.C. § 112 First Paragraph

Claim 5 also stands rejected under 35 U.S.C. § 112, First Paragraph for enablement. The Examiner asserts that the claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant need not have actually reduced the invention to practice prior to filing in order to satisfy the enablement requirement under 35 U.S.C. §112, first paragraph. MPEP §2164.02 (citing *Gould v. Quigg*, 822 F.2d 1074 (Fed. Cir. 1987)). Indeed, the invention need not contain a single example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation (*In re Borkowski*, 422 F.2d 904, 164 U.S.P.Q. 642 (CCPA 1970)), and "representative samples are not required by the statute and are not an end

in themselves" (*In re Robins*, 429 F.2d 452, 456-57, 166 U.S.P.Q. 552, 555 (C.C.P.A. 1970)). Thus, 35 U.S.C. § 112, first paragraph, enablement does not require any working examples.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. MPEP §2164.01 (citing *In re Angstadt*, 537 F.2d 498, 504 (C.C.P.A. 1976)). The fact that experimentation may be complex does not necessarily make it undue if the art typically engages in such experimentation. *Id.* Further, the specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. MPEP §2164.05(a) (citing *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991)). Therefore, enablement does not require a working example and experimentation is allowed so long as it is not undue.

Newly amended Claim 5 is enabled under 35 U.S.C. §112, first paragraph because the specification as filed amply supports claims reciting a method of administering a therapeutically effective amount of a compound of formula 1 to an animal in need thereof to antagonize substance P induction. Applicant respectfully directs the Examiner to paragraphs 0009 – 0017 of the Published Application (US 2006/0135558), where support is provided to show why the compounds of the present invention are suitable for use as substance-P antagonists and how the compounds inhibit the induction of substance P, thereby directly affecting disorders characterized by substance-P induction, specifically as discussed at paragraph 0009.

As such, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of Claim 5 under 35 U.S.C. § 112, First Paragraph.

III. Rejection under 35 U.S.C. § 112, Second Paragraph

Claim 8 stands rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim subject matter. In light of the amended claim language which now recites a process for the preparation of a compound of Formula 1, Applicant respectfully asserts that the rejection is moot and requests that the rejection of Claim 8 under 35 U.S.C. § 112 be withdrawn.

IV. Conclusion

In view of the foregoing, Claims 1 – 6 and 8 are in condition for allowance, and Applicant earnestly solicits a Notice of Allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this Application, the Examiner is invited to telephone the undersigned at the number provided. Prompt and favorable consideration to this Amendment and Reply is respectfully requested.

Respectfully submitted,
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